[Emblem] [Illegible handwritten notations]...
Laboratorios Belmac, S.A.

--Preparation of products for *Ethypharm* or its clients with the following personnel from our payroll:

--1 technician: Mateo Gasca
--1 production worker
--1 worker for filling capsules

Belmac shall issue monthly bills at cost for substances which are purchased for *Ethypharm,* as they are supplied.

Increases in personnel in relation to the team indicated herein shall result in increases in billing, if such a situation arises.

Billing shall be independent of the number of batches being produced and independent of volume.

I shall greatly appreciate your approval as promptly as possible.

Sincerely yours,

[Illegible signature]
Signature: Angel Perez de Ayala

EP 004723

éthypharm
Marques de la Ensenada,16
28004 Madrid – España
tel. (1)3085681
Fax. (1)3199159

TELEFAX

Date/FECHA: *4/10/95*

To/A: *Dr.González*
Firm/COMPAÑIA: *Belmac*
No.FAX:

From/DE: *Eloy González* No.págs: *1*

Según acordado adjunto enviamos el texto que básicamente creemos debe aparecer en la carta que deben recibir nuestros clientes para aclarar la relación Belmac–Ethypharm:

"A quien pueda interesar:

Belmac posee unas instalaciones en Zaragoza–España, aprobadas por el Ministerio de Sanidad, para fabricar medicamentos. Una parte de estas instalaciones ha sido cedida a Ethypharm para fabricar varios productos en forma de microgránulos. Estas instalaciones cumplen con la normativa europea sobre GMP y GLP (adjuntamos certificado GMP).
El personal pertenece a Belmac, pero la maquinaria y know–how empleado en la fabricación es propiedad de Ethypharm, quien supervisa las fabricaciones comprobando que se realizan según sus exigencias.
En concreto en esas instalaciones fabricamos el producto omeprazol, nombre comercial Belmazol 14 cápsulas de 20mg. Este producto ha sido registrado en el Ministerio de Sanidad español utilizando la documentación propiedad de Ethypharm. Por tanto los microgránulos de omeprazol se fabrican según las guías de fabricación aportadas por Ethypharm".

Pensamos que este texto deberá emitirse para cada cliente en particular, lo cual consultaremos con Francia.

Por su puesto pueden incluir las modificaciones que crean oportunas. En espera de sus comentarios, saludos cordiales.

Eloy González

EXHIBIT
Azetia 6
6/27/06

ETHYPHARM
[address and phone number]

Date: 10/4/95
To: Dr. Gonazlez
AT Belmac
From Eloy Gonzalez

According to what we decided, attached we are sending the basic text that we think needs to appear on the letter that our clients must receive in order to clarify the Belmac-Ethypharm relationship:

"To whom it may concern:

Belmac posseses several facilities in Zaragoza-Spain, approved by the Ministry of Health, to make medicine. One part of these facilities has been given to Ethypharm to make several products in the form of microgranules. These facilities comply with the European norms on GMP and GLP (we enclosed GMP certification).

The personnel belongs to Belmac, but the machinery and know-how employed in the manufacturing are the property of Ethypharm, who supervises the manufacturing, verifying that their standards are met.

Specifically in these facilities we make the product omeprazol, commercial name Belmazol 14 capsules of 20mg. This product has been registered in the Spanish Ministry of Health using the documentation property of Ethypharm. Therefore the microgranules of omeprazol are made according to the guidelines of manufacturing given by Ethypharm."

We think that this text should be given to each individual client, about which we will consult with France.

Of course, you can include the modifications they see fit. We await your comments and send warm salutations.

Eloy Gonzalez
[signature]

3199159

Telefax

Para: Mrs. Dubois / Debregeas / [illegible]
De: A de Basilio
Fecha 21-1-97 Nº Hojas: 1

Impresos Post-it™ 7669 3M

Fax 319 91 59
Telex: 23581 CENCO

enviado
enviada

A: CLEMENTE GONZALEZ (BELMAC)
DE: ADOLFO DE BASILIO (ETHYPHARM)

Fecha: 20/1/97
Páginas: 1

Estimado Dr. González,

Hemos sido convocados por nuestra central para la toma de decisiones de los asuntos pendientes con BELMAC y para la presentación de los presupuestos 1997. Después de un largo debate, hemos llegado a las siguientes conclusiones:

A pesar del esfuerzo realizado recientemente por BELMAC para mejorar los rendimientos de fabricaciones y consecuentemente el costo para ETHYPHARM, éstos, según nuevos cálculos, siguen sin ser rentables para nuestro grupo.

Como ya hemos podido ver en la pasada reunión en Zaragoza, los márgenes de las fabricaciones de microgránulos de ETHYPHARM son reducidos. Estos márgenes de fabricación no son suficientemente altos para cubrir los costos facturados por BELMAC.

El deseo de ETHYPHARM ha sido fabricar toda la producción de la filial española en Zaragoza. BELMAC no dispone aún de una estructura GMP que permita exportar a determinados países. Las GMPs no han llegado al nivel requerido por algunos de nuestros clientes como hemos podido comprobar después de la visita de auditoria de HMR y la confirmación posterior de nuestro departamento de QA. Según este informe, el estatus GMP no cumple con la legislación española ni con las normas de la U.E.

La política de trabajo que se ha seguido hasta la fecha con BELMAC no ha sido la apropiada por lo que hemos decidido transferir las fabricaciones de los principios activos libres de patente a una de las fábricas del Grupo ETHYPHARM y parar la producción de omeprazol hasta que la situación de patentes nos permita fabricarlo en alguna de las fábricas de nuestro grupo.

El próximo día 23 de Enero, tendremos una reunión en Francia con UQUIFA en la que será debidamente informado sobre la situación actual.

Rogamos transmitan estas decisiones a su casa matriz en EEUU.

En espera de sus comentarios al respecto le saluda cordialmente,

Adolfo de Basilio

EXHIBIT
DEBREGEAS
No. 29
MS 7-11-06

EP 006617

TO: CLEMENTE GONZALEZ (BELMAC)

FROM: ADOLFO DE BASILIO (ETHYPHARM)

Date: 1/20/97

Dear Dr. Gonzalez,

We have been summoned by our mother company to take a decision regarding the pending matters with BELMAC and for the presentation of the 1997 budgets. After an extended debate, we have reached the following conclusions:

In spite of the effort recently made by BELMAC to improve the manufacturing productivity and consequently ETHYPHARM's cost, these, according to new estimates, are still not profitable for our group.

As we have already been able to see in the last meeting in Zaragoza, margins for the manufacturing of ETHYPHARM's microgranules are reduced. These manufacturing margins are not sufficiently high to cover the costs invoiced by BELMAC.

ETHYPHARM's desire has been to manufacture all the production of the Spanish branch in Zaragoza. BELMAC does not have yet a GMP structure that allows to export to specified countries. The GMPs have not reached the level required by some of our clients, as we have been able to verify after the audit of "HMR" and the later confirmation of our department of "QA." According to this report, the GMP status does not comply with the Spanish legislation nor with the E.U. norms.

The work policy that has been followed to date with BELMAC has not been the appropriate one, so that we have decided to transfer the manufacturing of our active principles free of patent to one of the factories of the ETHYPHARM Group, and to stop the production of omeprazol until the patents' situation allows us to manufacture it in one of the factories of our group. Next Januray 23rd, we will have a meeting in France with UQUIFA during which they will be properly informed of the present situation.

We ask you to transmit these decisions to your mother company in the U.S.

We are awaiting your commentaries on this matter.

Warm regards.

Adolph de Basilio

éthypharm
Marqué
28004 M
Telex 23581 CENCO

Teletax
Nº fax:
Para: Mr. LEDUC DUBOIS
De: A de Basilio
Fecha: 28-1-97
Nº Hojas: 2

A: Clemente González (BELMAC)
DE: Adolfo de Basilio (ETHYPHARM)

Fecha: Madrid a 27 de Enero de 1997
Páginas: 2

Estimado Dr. González,

Como continuación a nuestro fax del pasado 20 de Enero y posteriores conversaciones telefónicas, pasamos a ampliar dicho fax por petición suya:

1. NORMAS DE FABRICACION

El pasado 13 de Febrero de 1996, la responsable de normas de nuestra central visitó las instalaciones de Zaragoza emitiendo un informe el cual enviamos resumido y traducido el 20 de Mayo de 1996. En él se reconocían los avances realizados por BELMAC desde su primera visita en 1992 aunque debía mejorar sus procedimientos de trabajo y crear documentos de apoyo a fabricación y control.

El pasado 7 de Noviembre recibimos la visita de un experto enviado por CHELSEA (HMR), cliente de UQUIFA, quien emitió un informe negativo en especial sobre el departamento de control analítico (pedir información a UQUIFA).

Después de la visita del pasado mes de febrero, estaba previsto que nuestro departamento de normas volviese a BELMAC para comprobar la instalación de la nueva máquina y ver como se había avanzado en la actualización de las normas de BELMAC. Esta inspección confirma el informe negativo del experto enviado por el laboratorio americano y que no sólo no se ha avanzado sino que se ha retrocedido. Acabamos de recibir el informe que les enviaremos una vez esté traducido.

En ninguno de estos informes figuran puntos en contra de las instalaciones, paredes o circuitos realizados según las normas GMP. Son los procedimientos de trabajo y la documentación de fabricación y control los que no están haciéndose según las normas.

EXHIBIT
Deposition
No. 30
MS 7-11-06

EP 006615

A-359

3199159

ethypharm

2. VISITA DEL TÉCNICO ITALIANO

La visita del técnico italiano que les anunciamos es únicamente para instalar una pieza que le falta a la nueva máquina y la posterior visita de los técnicos franceses es para comprobar (validar) el trabajo del técnico italiano así como recepcionar oficialmente la entrega de la máquina según mandan las normas GMP.

3. FUTURAS FABRICACIONES EN BELMAC

4. PAGO DE FACTURAS PENDIENTES

5. APROVISIONAMIENTO DE OMEPRAZOL CUANDO ETHYPHARM NO FABRIQUE EN BELMAC

6. FECHA DE SALIDA DE BELMAC

Los últimos puntos (3, 4, 5 y 6) así como el resto de los temas al respecto serán tratados directamente en una próxima reunión. El Sr. Dubois se desplazará a Nueva York y podrá entrevistarse con el Sr. Murphy el próximo lunes 3 de Febrero.

En espera de sus comentarios, le saluda cordialmente,

Adolfo de Basilio

c.c.: P. Debregeas/ G. Leduc/ C.Dubois/ E. Igonet

NOTA: El Sr. Debregeas no ha recibido ningún fax del Sr. Murphy. Les rogamos lo envíen al nº de fax de su despacho en París: (33)-1-41121730

[there appears a rectangular label which reads: "Telefax. Fax No.: (blank space) For: Mrs LEDUC DUBOIS DEBREGEAS. From: A. de Basilio. Date: 01-28-97. No. of pages: 2"]

To: Clemente González (BELMAC)
From: Adolfo de Basilio (ETHYPHARM)

Date: Madrid, January 27th, 1997.
Pages: 2

Dear Dr González,

Continuing our fax dated January 20th and the subsequent telephone conversations, we expand the aforesaid fax as requested:

1. MANUFACTURING RULES

On February 13th 1996, the person responsible for the rules of our head office visited the facilities in Zaragoza and issued a report which we sent in an abridged version and translated on May 20th, 1996. The abovementioned fax detailed the advances made by BELMAC since its first visit in 1992 although it had to improve its working procedures and draft support documents for manufacture and control.

On November 7th, we received the visit of an expert sent by CHELSEA (HMR), client of UQUIFA, who issued a negative report especially on the analytical control department (ask information to UQUIFA).

After the visit in last February, it had been planned that our rules department come back to BELMAC in order to check the installation of the new machine and to see the progress in the update of BELMAC's rules. This inspection confirms the expert's negative report sent by the American laboratory and that not only have they not advanced, they have receded. We have received the report which we will send to you once it has been translated.

None of these reports include points against the facilities, walls or circuits made in accordance with GMP's rules. The work procedures and manufacturing and control documents are not being made in accordance with the rules.

ethypharm

3199159

2. VISIT OF ITALIAN TECHNICIAN

The Italian technician's visit which we announce is only to install a part which is missing from the new machine and the subsequent visit of the French technicians is to check (validate) the Italian technician's work as well as to officially receive the machine in accordance with GMP's rules.

3. FUTURE MANUFACTURES IN BELMAC

4. PAYMENT OF PENDING INVOICES

5. PROVISIONING OF OMEPRAZOL WHEN ETHYPHARM DOES NOT MANUFACTURE IN BELMAC

6. DATE OF EXIT OF BELMAC

The last items (3, 4, 5 and 6), as well as the rest of the topics related to them, will be dealt with directly in the next meeting. Mr Dubois will go to New York and meet Mr. Murphy on Monday February 3rd.

Looking forward to hearing your comments,

Adolfo de Basilio

Cc: P. Debregeas / G. Leduc / C. Dubois / E. Igonet

NOTE: Mr Debregeas has not received any fax from Mr Murphy. Please send it to the fax number of his office in Paris: (33)-1-41121730

EP 006616

01/28/97 14:44 ☎ BENTLEY PHARM. ☑001

CD → FI/RT
Corr: Lp 3

FACSIMILE
TRANSMITTAL

→ CD/Lc/Po
A&B.

Bentley Pharmaceuticals, Inc.
One Urban Centre
Suite 548
4830 West Kennedy Blvd.
Tampa, FL 33609-2517

Telephone (813) 286-4401
Facsimile (813) 286-4402

To:	Patrice DeBregeas
Company:	Ethypharm
Fax #:	011 33 1 41 12 17 30
From:	James R. Murphy Chairman & CEO
Date:	January 28, 1997
Subject:	Lab. Belmac Manufacturing for Ethypharm

Dear Patrice,

I am writing with regard to the fax that I received from your Spanish office. I am confused because, ever since I assumed control of Laboratorios Belmac, I have received nothing but extremely positive comments from your Spanish staff specifically, Sr. Basilio, who said: That the Belmac operation is now more efficient, more cooperative, more pleasant to work with, and beyond this he noted our high degree of sincerity and integrity.

Sr. Basilio's comments always were highly complimentary to me and our staff.

Even though Laboratorios Belmac has not received payment from Ethypharm in the past year, we have continued to provide Ethypharm with product in a diligent and highly professional manner. Belmac's actions have documented our good faith, as well as confirmed our level of commitment and cooperation with your organization. Are you aware of any other company that would be as tolerant as Belmac has been? The amount of money overdue to date is approximately 60 million pesetas.

Also let me refresh your memory that we attempted in good faith, on numerous occasions, to establish a contractual relationship between our companies which Ethypharm declined to negotiate to conclusion.

EXHIBIT
MURPHY
22
9/9/06 SLB

EP 002106

A-363

6947-EX00220124

According to this fax, the Ethypharm renovated area does not comply with GMP requirements. Yet, Ethypharm has requested reimbursement based upon a claim that Ethypharm has spent money to bring the area into full compliance; further, Ethypharm management oversees the technology applications to manufactured products, therefore, it would seem illogical for Belmac to consider reimbursement for an area, that by your own admission, does not conform to GMP standards.

It appears that Ethypharm wants the luxury of a facility, personnel, export licenses, manufacturing license, administration, shipping, purchasing, etc., but without the costs or liabilities associated with the maintenance of personnel, facilities, employee indemnities, etc.

I suggest we schedule a meeting in Madrid to discuss the future of the relationship between our organizations and on the agenda we will be prepared to discuss:

- Arrangements to receive payments that are long overdue
- *Belmac's proposal for a structure that would provide a profitable operation* for Ethypharm in Spain.
- *Obtain an understanding of what problems (if any) exist since I have only* heard compliments from Ethypharm.
- And if you wish, discuss the orderly departure of Ethypharm from the Belmac facilities.

I suggest the following people be in attendance during the first part of Feb.:

Ethypharm	Lab. Belmac
Patrice DeBregeas	Jim Murphy
Adolpho Basilio	*Clemente Gonzolas*
	Dr. Monterde
	Mateo Gazca

Best Regards,

Jim

LABORATORIOS BELMAC, S.A.
C/Teide, 4 Planta Baja
Parque Empresarial La Marina
28700 San Sebastian de los Reyes
Madrid

FAX

DATE: 31/01/97
FAX Nº: 91 388 76 47
FOR: BELMAC – MADRID
Att.: MR. GONZALEZ
From: LABORATORIOS BELMAC – ZARAGOZA

Nº of pages (including this): 5

SUBJECT:

MANUFACTURING RULES

EXHIBIT
Azpeita 10
6/27/06

1ST MANUFACTURING RULES

1ST Expert report HMR; unknown, as a result of which we have not been able to carry out the corrections or the improvements that could have been indicated therein.

2nd Following the visit of Madame Gavoille in February, the report she made was not sent until three months later, even so Belmac began to introduce improvements in order to alleviate whatever it could at that moment, these recommendations made by the department of Quality Guarantee of Ethypharm France.

Reference to the suggestions made:

Storage:

Positive points in reference to the Belmac documentation:
- Stock ordered
- Quarantine and accept in force
- Presence of extractor hood

The humidity and temperature are not controlled given that in the 25 years during which the raw materials and empty capsules have been stored in this way no alterations in these substances have been observed.

Air filtration system.

The maintenance and cleaning report under the responsibility of Belmac is correct. The air filtration system was implemented by the technicians of Ethypharm, and so it is their responsibility to carry out the maintenance procedures and supervision of this air system.
Also as a result of the implementation of the system of air filtration / impulsion, the installation of appliances to measure the pressure difference was not deemed necessary. The validation of the air system should have been carried out when it was put into operation, which took place under the direction of Ethypharm.

Internal storage room.

Ethypharm was unclear about whether some products could be rejected or not. From this date on, a decision was made regarding those which could indeed be rejected, and it was also decided that no more intermediate products were to be stored in the internal warehouse, but rather that these should be sent to quarantine areas for such products, with the warehouse given over solely to raw materials.
The dust from the packaging is cleaned regularly and always before entering the weighing room.

Weighing room.

- The room is clean, therefore Belmac keeps it in perfect condition.

- The installation of the extractor hood was envisaged on construction of the chambers by Ethypharm, but for various reasons it was never installed, even though measurements have been taken on a number of occasions by companies sent by Ethypharm.
The daily control corresponding to Belmac is carried out daily.

The weights were supplied by Mr. Bernabé personally, until such time as Ethypharm provides the remaining weights in order to reach 120 kg which is why this section appears in the book, although after this visit it was eliminated with a line through it.

Vat room.

- Cleaning and maintenance, responsibility of Belmac, are very good.
- A check of the residual phosphates was carried out until the cleaning process was validated, ascertaining that every time cleaning was carried out it came up negative, as a result of which it was carried out only every certain number of lots.
- Ethypharm should provide the cleaning validation procedure for the different active ingredient

Washing Room.

All of the cleaning material has been labelled.
The brushes should be provided by Laboratorios Ethypharm.

Encapsulating Room.

- The room is clean and tidy.
- The calibration of balances procedure drawn up by the control department has been implemented.
- The thermo-hygrograph register is controlled weekly.
- The capsulating-machine was working for at least 6 months in the installations of Ethypharm France and was subsequently sent without its cleaning procedure.

Hygiene of the production / environmental control personnel:

- Clothing in a perfect state of cleanliness.
- In order to avoid the operators wearing the garments they wear in the non-classified or clean areas, Ethypharm did not take into account the construction of a changing room on designing the micro-granules area, as Belmac did in the areas of production of the rest of the pharmaceutical forms.

Manufacturing water.

- An attempt is being made to instigate a microbiological control procedure, although at present water is not used in the manufacture of microgranules.

Documentation.

Documental management of basic documents. *(1)*

There are two Omeprazole dossiers, neither of which reflect how Omeprazole is manufactured. Although Belmac has made notes in one of these and has drawn up a provisional procedure for the manufacture of Omeprazole in the turbine G.S., furthermore they are written in French.
The method of analysis of the Omeprazole pellets provided by Ethypharm is not standardised and also according to the indication of Mr. Ourry it is provisional, plus it is written in French.
For the aspirin, since 1992 Belmac has been carrying out a procedure that is neither standardised nor signed in order to be able to carry out the manufacture of the pellets of this active ingredient
The aspirin analysis procedure was provided by Madaus, although with modifications and it has not been standardised.
For lansoprazole there is a procedure which is characterised by a general blank, and it has had to be filled in by hand for each lot, since the year 1993.
The analysis procedure for this, apart from presenting significant errors and defects, is neither standardised nor duly signed, plus both are in French.
The manufacture procedure for Piroxicam, has presented the same defects as Lansoprazole since January of the year 1996.
The control procedure was provided by Laboratorios FAES.
The manufacture procedure for Indomethacin was provided by Ethypharm France, translated by Ethypharm Spain, and the translation was checked by Belmac, but then the procedure was not submitted normalised and signed by Ethypharm France, for its use. Therefore the translated copy that has not been normalised is being used.
The methods of analysis of micronised Omeprazole are normalised by Belmac for the control of the active ingredient used for the manufacture of its speciality Belmazol, but Ethypharm has never provided any procedure whatsoever.
With regards to the HP-50 and Talcum procedure it is not carried out on the entirety, because the means at the disposal of Belmac are not sufficient, but the same controls are always carried out for each and every one of the lots analysed.

Procedure A.Q. *(1)*

- The procedures provided by Ethypharm in 1992 were delivered to Belmac in order that they take effect given that the microgranules manufacturing area was a simulation of the manufacturing zones in Ethypharm France.
- At present either there are attempts to implement the remaining procedures or they have already been implemented, such as the calibration of the control material, for instance. In spite of the fact that Ethypharm has not provided any information or help as was agreed for the implementation of these procedures.

Case of release procedure for microgranules and capsules lots of Ethypharm.

In spite of the fact that this situation was known to Mr. De Basilio, and accepted by him, from January 1997 on it has changed, because Mateo Gasca is no longer responsible for control. *(3)*
However, even so, Ethypharm has still not given a reply regarding the person who shall be responsible for the release of lots.

Summary.

Therefore, due to the facts and information reflected in the report, as well as in the last paragraph of the Fax of January 27th, 1997, the part corresponding to Belmac with regards to maintenance of rooms and cleaning of the same, as well as the circuits are G.M.P.
Furthermore, in other facets of their responsibility they are making efforts to improve the least positive aspects.
With regards to the procedures and measures that Ethypharm should provide in order to improve this situation, the only thing it has done has been to translate the manufacturing and analysis procedure of Indomethacin.

On the other hand, Laboratorios Belmac wishes to clarify: That even though in the reports indicated in the Fax of January 27th, 1997, no defects appear in the installations and the walls of the microgranules zone, drawn up under the direction and control of Ethypharm, the Inspector, Mrs. Estrella Sintas, from the Spanish Ministry for Health in an inspection of said installations, made a series of clarifications of points that needed to be improved in order for said installations to comply with the G.M.P. Standards in future inspections. These were:

- The microgranule Manufacturing rooms are not classified rooms.
- The flow of air in the room (brushed), in the microgranules zone, was not suitable due to the poor location of the return of this air.
- Absence of a changing room exclusively for the microgranules zone.

Plus, self-inspections carried out by Laboratorios Belmac have detected a series of defects impeding the capacity to work in accordance with the G.M.P. standards, which are detailed below:

- The state of the walls from day one has been bad, presenting numerous cracks, a situation that Ethypharm has not been capable of correcting.

- The extractor hood has not been installed in the weighing room.

- All types of furnishings are lacking in order for the facility to comply with the G.M.P. standards. Belmac has been the company that provided the minimum necessary in order to manufacture the microgranules. *(2) (5) (9) (15)*

- There is no zone, not even a shelf to allow for separation and ordering of clean material from material that is not clean.

- Defects in the warehouse due to a lack of shelving, for the correct location of the raw materials.

- Although a list of the minimum material in stainless steel (buckets, spades, deposits, agitators, folders, etc.) necessary for the manufacture of

microgranules in accordance with the G.M.P standards was made, this has not been attended to by Ethypharm.

- An adequate recipient for the cleaning of the nets of the sieve, thus preventing the high risk which currently exists of crossed contamination that inadequate cleaning can lead to, has been repeatedly requested.

Zaragoza, January 31st, 1997.

Ethypharm

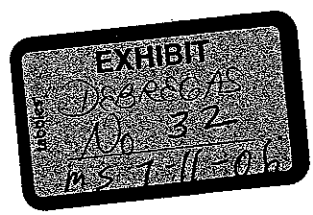
FAX FRONT PAGE

To: Mr. James R. MURPHY
Company: BENTLEY PHARMACEUTICALS
Fax number: 00 1 813 286 4402

From: Claude DUBOIS
Company: ETHYPHARM (Saint Cloud)
Telephone: 33 1 41 12 17 20
Fax number: 33 1 41 12 17 30

Date: 14/02/97
Page (s): 6

Letter mailed on February 13th, 1997



éthypharm
Direction Générale et Médicale
194, Bureaux de la Colline
92213 SAINT-CLOUD - FRANCE
Visioconférence (33) 01 41 12 00 75
Tél. (33) 01 41 12 17 20
Fax (33) 01 41 12 17 30

BENTLEY PHARMACEUTICALS
One Urban Centre, Suite 548
4830 West Kennedy Blvd.
TAMPA, FL 33609-2517
USA

Ref : VB/0297/13

Saint Cloud, Thursday 13 February 1997

For the attention of Mr. James MURPHY

Dear Jim,

After our meeting, I think that our exchanges cleared certain misunderstandings about our position in Spain.
We can only maintain manufacturing there if :

- we are sure that an economical number of MHB batches can be produced. Our target is 40 MHB batches. That can be achieved with one shift according to our calculation, even if we have to drop manufacturing of other products or switch them to France.
- G.M.P. procedures are improved according to our last Quality Insurance report, that you will find herewith.
- Cost remain economically viable.

We propose that for the next six months we continue manufacturing in Saragossa. 20 batches of MHB have to be produced before the summer holidays and all priorities given to this objective.
Meanwhile, requested G.M.P. modifications have to be largely implemented. You suggested that your consultant in quality should visit Saragossa, we agree that this has to be done in the best delays.
Monthly rent will be maintained at the present level for this six months and payment of the existing debit scheduled on the year (affidavits will be signed by us to allow you accounting treatments).
After this six months, if objectives are met, we shall re-evaluate the rent on a yearly basis reflecting the number of MHB batches manufactured in exceed of 20, and devise ways to increase production over 40 batches per year.

Looking forward to our meeting in Europe in a very next future.

Best regards.

C. Dubois

Claude Dubois

EP 004677

A-372

January 2, 1997

Audit of the ETHYPHARM production site in Saragossa

Date : December 10, 1996

Persons met :

Mateo GASCA
- Head of Quality Control, Manufacture and Encapsulation of the microgranules produced in the ETHYPHARM area
- Head of BELMAC Quality Control

ETHYPHARM representatives present :

- Adolfo de BASILIO
- Domingo BERNABE
- Pierre FONTANI

Objective :

To check the compliance of the production carried out on behalf of ETHYPHARM on the BELMAC/ETHYPHARM site in Saragossa with the EEC GMP.

Programme :

Assessment of the follow-up to the quality actions reommended in M. GAVOILLE's report of 08.03.1996, following her audit visit on 13.02.1996.

Audit of the quality system applied to the ETHYPHARM microgranules manufacturing activity.

Progress of the quality points with reference to the assessment made by M. GAVOILLE on 13.02.1996.

1 - PRODUCTION PREMISES AND EQUIPMENT

None of the actions recommended for improving quality has been put into effect.

2 - DOCUMENTATION

2.1 - Technical documentation on MHB

Manufacture :
There are no official ETHYPHARM documents **(critical defect).**
The operators work with documents proposed by ETHYPHARM France.

Control of Starting Materials, Intermediate Products and Finished Products :
There are no official ETHYPHARM documents **(critical defect).**
The documents used are BELMAC documents with UQUIFA methods and specifications.

2.2 - Quality Assurace Procedures

Only BELMAC procedures are used throughout the site.

In the ETHYPHARM manufacturing area, only a few record forms relating to ETHYPHARM procedures dating from 1992 are used. These procedures are kept in a filing box in the storage area **(critical defect).**

2 - ORGANISATION

One and the same person, Mateo GASCA, is in charge of manufacture and control **(critical defect).**

Audit of the ETHYPHARM production area

① **Warehouse - ETHYPHARM Intermediate Storage**

The two conventional pans replaced by the GS are being kept temporarily in this room, and the storage of the materials is disorganised by the resultant clutter **(major defect).**

② **Weighing room**

The 20-kg weight used for calibrating the balance is placed directly on the floor, with no particular protection **(major defect).**

③ **Conventional pan rooms**

The rooms are not identified according to the activity pursued in them **(major defect).**

④ **GS pan room**

No production was under way, but the following items were present in the room :
- a sachet of microgranules with no label (microgranules stated to be MHB waste)
- plastic trays containing unidentified granules (stated to be neutral microgranules)

(critical defect).

⑤ **Solution preparation room**

This room is also used for storing production equipment.

A damaged sieve screen was present with the other screens, on the one and only sieve storage rack **(critical defect).**

A container labelled with only the words PVP 12 % was present in the room **(critical defect).**

⑥ **Capsule filling room**

At the end of the work day : the room was untidy and the surface of the machine covered with powder from the batch being manufactured **(critical defect).**

The thermohygrograph recording was not noted (4 tracings on the same sheet) **(major defect).**

⑦ **Washing room**

At the end of the work day :
- the room was untidy and had not been cleaned or disinfected **(critical defect).**
- MHB microgranule waste was present in unlabelled sachets, placed directly on the floor **(critical defect).**

The equipment is incomplete :
- there is nowhere to put away the cleaning equipment and products.
- there is no sink suitable for cleaning the sieve screens.

(critical defect).

CONCLUSION

The degree of criticalness of the deviations from the EEC GMP shows that it will be necessary to implement the essential quality points in order to comply with European regulations.

Pierre FONTANI
Quality Assurance Assistant

B

P) CD/ALB/PO

Madrid, 20 Marzo 1.997

CG PSM

Cher Monsieur:

Malgré que notre President, Mr. Murphy va s'addresser a Mr. Dubois en repondant a sa lettre du 13.02.97, nous voudrions vous faire parvenir notre opinion ainsi que celle des techniciens relationés avec le developement du procedé de fabrication des micro-granules (pellets) d'Omeprazol dans la nouvelle machine, turbine G.S., installé a la fin d'Octobre, 1996.

Depuis cette date, on a fait quatre lots de M.H.B., et un lot de L.A.P., mais il n'as pas eté quen Janvier 1.997 qu'on a comencé a fabriquer regulierement le M.H.B, dont nous avons fait trois lots.

Pendant ce temps il a eté necessaire la visite d'un technicien de la maison G.S., pour essayer d'ameliorer le systme de messure de la depression que n'est pas encore fini. Cela vous donnera la vision de que le procedé n'est pas 100% au/point.

C'est vrai que chaque jour, notre personnel, avec l'inestimable collaboration de Mr. Bernabé, s'adapte mieux aux caracteristiques de la nouvelle machine et que, progressivement, la qualité des pellets d'Omeprazol c'est beaucoup amelioré.

Dans notre opinion, que nous esperons sera partagé par vous, on dois continuer, previsiblemente jusqua la fin juillet prochain, a fabriquer au méme rytme actuel pour arriver a obtenir un produit de la plus haute qualité, tout en repondant aux specifications les plus exigeants de n'importe quel client.

Si nous pretendons fabriquer avec notre encore faible experience actuelle, avec le nouvelle machine a toute allure, pour faire quatre lots par mois, pour arriver aux chiffres de votre budget, nous risquons d'obtenir un produit irregulier que peut être rejeté por vos clients.

Nous voulons vous faire savoir que notre intention c'est de maitre tous les resources necessaries, tant du point de vue humains, comme techniques, pour arriver a notre but comun de fabriquer un produit de qualité maximale, avec un potenciel de futur trés important.

En ce qui concerne l'implantation compléte des G.M.P. de la U.E., nous sommes disposés a prendre toutes les messures necessaires pour arriver a l'acomplissement des standards avant juillet 1.997, dans la certitude que ca aidera a obenir la meilleure qualité des pellets.

BELMAC

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Nous vous proposons un comité mixte, Ethypharm-Belmac, pour l'etablissement des besoins et le calandrier pour arriver a ce but.

Nous voulons, finalement, vous transmetre notre meilleure disposition pour obtenir les niveaux de qualite exigés et pour que ce soit un trés bon affaire pour les deux compagnies.

Nous sommes a votre disposition dans le cas dont vous desirez avoir un rencontre personel à votre bureau.

Nous esperons aussi, etant donnéc la bonne volonté de notre President et sa flexibilité, qu'il sera assez facile d'arriver a un accord sur les sujets economiques.

Nous vous prions d'agreer a l'expression de nos sentiments les meilleures.

Clemente González Azpeitia
Directeur General

LABORATORIOS BELMAC S.A. [Laboratory]

Madrid, March 20, 1997

Dear Sir,

Although our President, Mr. Murphy, is going to address Mr. Dubois in response to his letter dated 02/13/97, we would like to let you know our opinion as well as that of the technicians related to the development of the manufacturing process of microgranules (pellets) of Omeprazole using the new machine, G.S. turbine, installed in late October, 1996.

As from that date, four M.H.B. batches and a L.A.P. batch were manufactured, but it was only in January 1997 that M.H.B. started to be manufactured regularly, when three batches were produced.

During that time, the visit of a technician to the G.S. office was required in order to try to improve the system designed to measure pressure, which is not finished yet. This conveys the idea that the process is not 100% finished.

It is true that every day, our staff, with the invaluable collaboration from Mr. Bernabé, is adapting to the characteristics of the new machine and progressively, the quality of pellets has been improved significantly.

According to our opinion, which we hope you will agree with, we must continue to manufacture at the current rate until the end of next July in order to obtain a product of the highest quality, in response to the most demanding specifications of any client.

If our intention is to carry out manufacturing using our limited experience, with the new machine going full steam ahead, in order to manufacture four batches a month, so as to reach the figures set forth in your budget, we run the risk of producing an irregular product that may be rejected by your clients.

We would like to let you know that our intention is to use all required resources, from the human as well as the technical point of view, in order to manage manufacturing a product of the highest quality, with a very important potential future.

As regards the whole implementation of EU GMPs, we are willing to take all necessary measures to comply with standards before July 1997, with the conviction that this will help us obtain the highest quality pellets.

We propose a mixed committee, Ethypharm-Belmac, to determine the needs and the schedule in order to accomplish such end.

Finally, we would like to express that we are willing to meet the required quality standards so that both companies may benefit from this business.

We shall be available for a meeting at your office at any time you decide.

We also hope, taking into account our President's good will and flexibility, that an agreement on economic matters shall be easily reached.

Very truly yours,
Clemente González Azpeitia
General Director

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ESPAGNE

REF :SD0497/067

Saint Cloud, le mardi 1er avril 1997

A l'attention de Mr. C. GONZALEZ AZPEITIA

Cher Monsieur,

Merci pour votre courrier du 20 Mars 1997. Nous attendons la réponse de votre Président à la lettre du 13 février 1997, mais d'ores et déjà nous vous communiquons nos commentaires sur votre lettre.

En ce qui concerne la mise au point des G.M.P., nous pensons que comme suggéré à Mr. Murphy, une visite à Saragosse de votre Conseil Qualité pourrait être utile pour une meilleure compréhension entre nos départements Assurance Qualité.

Ainsi, nous pourrons au sein d'un comité mixte suivre la mise en place des modifications nécessaires que les deux parties auront entériné, mais certaines procédures mentionnées dans notre rapport peuvent être déjà mises en place.

En ce qui concerne la fabrication des microgranules de MHB, nous pensons qu'après les trois premiers lots, la phase de mise au point doit être terminée et la fabrication atteindre son rythme de croisière. Si nous n'avons pas l'assurance avant l'été que l'objectif de quatre lots mensuels est atteint d'une manière régulière, c'est, comme je l'ai dit à Mr. Murphy, tout le projet qui sera remis en question. Nous attendons donc de vos nouvelles à ce sujet mais nous ne pourrons pas repousser notre décision.

Nous vous prions de croire, Cher Monsieur, à l'expression de nos sentiments les meilleurs.

Claude Dubois

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Ref: SD0497/067

Saint-Cloud, Tuesday, April 1, 1997

To the attention of Mr. C. GONZALEZ AZPEITIA

Dear Sir,

Thanks for your letter dated March 20, 1997. We are looking forward to your President's answer to the letter dated February 13, 1997. However, we hereby let you know our remarks about your letter.

As regards the implementation of GMPs, we consider that, as suggested by Mr. Murphy, a visit to Zaragoza by your Quality Committee may be useful for a better understanding between our Quality and Insurance departments.

Accordingly, we may, by means of a mixed committee, carry out such modifications as shall be required by both parties, but certain procedures mentioned in our report may already be implemented.

As regards manufacturing of MHB microgranules, we consider that after the first three batches, the implementation stage shall be finished and a higher manufacturing rate shall be reached. If we are not sure before summer about the objective of regularly manufacturing four batches per month, the whole project shall be questioned, as pointed out by Mr. Murphy. We are looking forward to your remarks concerning these matters but we cannot postpone our decision.

Yours faithfully,

Claude Dubois

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813 286-4401 Fax 813 286-4402

For the attention of Mr. Claude Dubois

Dear Claude

Thank you for your fax dated April 9th, 1.997.

According with the opinion of your technicians and ours (Mr. Bernabe and Mr. Gasca), the industrial scale up is not yet completely finished, and the product can be improved although it should be acceptable for some of your clients.

To arrive at four batches per month, we need to appoint three or four additional employees with adequate training. The selection process was stoped when we received your fax of January 20, 1.997 announcing the termination of our collaboration. This process, needs to be re-started and the minimum training will be of three or four months, unless you send your qualified people to Zaragoza, and under Ethypharm´s responsibility.

Unfortunately I am not able to assist at the meeting that will be held at your Paris office, but we certainly wish to find together the best solution for both companies and I believe that you will find the most flexible position in Clemente González and his collaborators.

Regarding the improvement of G.M.P. we can ask a foreign consultant but we think that will be better to first establish a program between Q.A. people of our companies.

We are open to your decision.

I look forward to hearing from you.

Best regards,

James R Murphy

James R. Murphy

EXHIBIT
DEPOSITION
No. 34
MS 7-11-06